REMARKS

This is in response to the Office Action dated November 17, 2003. Reconsideration of the above-identified application, in view of the above amendments and the following remarks, is respectfully requested.

Claims 2-36 and 38-46 are currently pending.

Applicants appreciate the careful consideration and favorable treatment of the claims in which claims 38-46 were allowed and claims 7-17, 19-26, 28 and 30-36 were indicated as being allowable.

Claims 27 and 29 stand rejected under 35 U.S.C. 112, second paragraph, on the grounds of lack of antecedent basis for a claimed element. In response, Applicants have amended each of claims 27 and 29 to provide antecedent support for the claimed "prescribed criteria" feature. As a result, this rejection should be withdrawn.

Claims 2, 5 and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application No. 0526152. Applicants respectfully traverse this rejection for the following reasons. Initially, Applicants acknowledge the Examiner's comments in paragraph (11) of the Office Action where the Examiner states that Applicants did not explicitly claim that the first flow rate is one that flows within the first conduit and in order to more positively set forth the present invention, Applicants have explicitly stated in claim 2 that the claimed first detected characteristic is a flow rate of one of the fluids that flows within the first conduit that extends between the dialysis machine and the dialyzer. Applicants respectfully submit that the present Amendment to claim 2 does not require further consideration and/or searching since this feature and the argument were previously submitted to the Examiner. In addition, the allowed claim 38 contains a similar feature and thus, is a further indication that the amended claim 2 should be allowed.

The EP '152 reference is directed to a hemodiafiltration apparatus and while this apparatus does include a flow meter device and a control unit, there are one or more significant

differences between the control unit in the EP '152 reference and the present one. One difference is that the control unit in the cited reference controls a "dialysate" pump located in a conduit that connects to the dialyzer outlet, whereas, the present control unit in the claimed module controls a substitution fluid pump and hence controls the amount of fluid being diverted into the second conduit that is delivered to the extracorporeal circuit as substitution fluid. Moreover, the cited reference discloses a flow meter that is an integral part of the described hemodiafiltration system or apparatus. As is known in the art, the flow meter (e.g., differential flow meter) is an integral part of the ultrafiltration control system which is generally a required subsystem of a hemodialysis machine. Applicants respectfully submit that in the present scheme, the "flow meter" has nothing to do with the ultrafiltration control system. Instead, it is part of the present hemodiafiltration module that connects to a dialysis machine (that already has its own ultrafiltration control system). The present flow meter is used as a protective safety means to stop hemodiafiltration when the dialysis machine stops delivering dialysate fluid to the claimed module. Applicants respectfully draw the Examiner's attention to the fact that the claimed apparatus is a module that is neither a standalone dialysis machine nor a standalone hemodiafiltration machine and as such, the claimed apparatus includes flow meters in a conduit that is within the module.

As previously-mentioned, Applicants have amended claim 2 to recite that the first characteristic is a flow rate of one of the fluids that flows within the first conduit that extends between the dialysis machine and the dialyzer. This claimed feature is not present in the cited EP '152 reference. In addition, the arguments presented in the previous Amendment apply to the present rejection and therefore, are equally applicable against the cited reference.

Claims 2-3, 5, 6, and 18 stand rejected under 35 U.S.C. 102(a) as being anticipated by WO 00/06292. Applicants repeat the arguments present in the prior amendment with the added support in claim 2 now.

Once again, this cited reference is published to the present assignee and describes a method and apparatus for efficient hemodiafiltration. The apparatus includes a first dialyzer cartridge and a second dialyzer cartridge where fluid discharged from the first dialyzer cartridge is

mixed with substitution fluid before entering the second dialyzer cartridge. Hemodiafiltration occurs in both cartridges.

In rejecting the above claims, the Examiner states that the apparatus of the cited reference includes a control unit that is responsive to flow rate of the first fluid via a flow meter (10) and a flow rate of blood via a flow meter (26) to control a substitution pump.

Applicants respectfully traverse this rejection on the following grounds. While member 10 is a flow meter, its location and operation is not the same as the feature disclosed in the amended claim 2. Claim 2 has been amended to recite a system where a control unit is present and is responsive to a first detected characteristic of one of the first fluid and the dialysate fluid, both of which flow within the first conduit which is defined as being connected at one end to the dialysis machine and at the other end to a dialyzer. The claimed first detected characteristic is a flow rate of one of the fluids that flows within the first conduit that extends between the dialysis machine and the dialyzer.

In the cited reference, the flow meter 10 is placed in a conduit that receives fresh dialysate fluid and delivers it to sterilizing filters which filter the fluid for use as a substitution fluid that is introduced between the dialyzer cartridges. In other words, the flow meter 10 is disposed in the conduit that is described as the "second conduit" in claim 1 as opposed to being in the "first conduit" that is recited in claim 2. Applicants therefore respectfully submit that the flow meter 10 does not serve to detect a flow rate of a fluid in the first conduit since it is positioned within a line 2 which actually functions instead as the claimed second conduit.

In sum, Applicants respectfully contend that there is no disclosure or suggestion of detecting the flow rate of a fluid (e.g., dialysate fluid) as it flows from the dialysis machine to the dialyzer. In the cited reference, the conduit that most closely operates as the claimed first conduit is the conduit 41. There is a lack of teaching or suggestion of detecting a flow rate within this conduit 41. Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 2.

Claims 3-36 should be allowed as depending from what should be an allowed

independent claim 2, as amended. In addition, a number of claims contain patentable subject matter in and of themselves, as already indicated by the Examiner.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/06292 and further in view of Shaldon et al. Claim 4 should be allowed as depending from what should be an allowed claim 2. Further, the Shaldon et al. reference does not overcome the deficiencies of the primary reference. The object of the Shaldon et al. reference is to reduce patient symptoms by reducing the efficiency of the treatment. There are flow meters in the apparatus described in the patent; however, these are used in the same manner as described above (i.e., as part of an ultrafiltration control system). Shaldon et al. teach that it is desirable to reduce the efficiency (which can be accomplished by changing the substitution rate) based on a urea monitor in the spent dialysate stream.

Claims 38-46 have been allowed.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

By_____

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